REMARKS:

Claim Status

Prior to this amendment, claims 6-11 and 18-35 were pending, claims 6-11, 18-21, and 31-35 were withdrawn, and claims 1-5 and 12-17 were canceled. With the entry of this Amendment, claims 6-11 and 22-35 remain pending and claims 1-5 and 12-21 are canceled. Claims 6-11 and 31-35 are withdrawn, and claims 22-30 are under consideration. The Applicant agrees that claim 31 is directed to a non-elected invention and is not presently under consideration.

Information Disclosure Statement

The Office did not consider the International Search Report cited in the Information Disclosure Statement filed March 18, 2004. (Office Action at ¶ 5.) As a courtesy, the Applicant encloses an Information Disclosure Statement citing and providing a copy of the International Search Report issued for the related international application PCT/US06/07906. The Information Disclosure Statement also cites Moreno et al., discussed on page 14 of this paper.

Specification

Continuity Statement and Oath/Declaration

The Office objects to the specification as presenting an improper continuity statement and asserts that the application, while presenting no new matter, should be redesignated as a continuation-in-part, rather than a continuation. According to the Office, although the specification and drawings present no new matter, the application presents method claims which do not satisfy the requirements of 35 U.S.C. §§ 101 and 112. (Office Action at ¶ 10.) In the arguments presented below, the Applicant demonstrates that the claims satisfy the statutory requirements of 35 U.S.C. §§ 101 and 112 and requests the Office to withdraw this objection after considering these arguments.

The Applicant thanks the Office for pointing out that the specification should be amended to include the number of the patent that issued from Application No. 09/534,072, filed March 24, 2000 (hereafter referred to as "the parent application") and to specify that the instant application claims the benefit of the filing date of the parent application, which in turn claims the benefit of the filing date of the provisional application. (Office Action at ¶ 9.) The specification has been amended accordingly.

Browser-Executable Code

The Office objects to browser-executable code in the specification. (Office Action at ¶ 11.) The Applicant has amended the specification to remove the browser-executable code, which was found in the paragraph spanning pages 16-17 and the first full paragraph on page 29. Accordingly, the Applicant respectfully requests the Office to withdraw the objection.

Trademark Demarcation

The Office objects to the use of improperly demarcated trademarks. (Office Action at ¶ 12.) The specification has been amended to indicate the appropriate symbols of these trademarks. Accordingly, the Applicant requests the Office to withdraw the objection.

Antecedent Basis and Claim Support

The Office objects to the specification for failing to provide proper antecedent basis for the claimed subject matter and failing to provide clear support for the claim language. It asserts that there is no description of the claimed method comprising the active step of detecting a PCGEM1 nucleic acid in a biological sample. It also asserts that, while the disclosure describes detecting a marker of prostate cancer by hybridization with an oligonucleotide probe and describes a method of detecting prostate cancer by detecting PCGEM1 RNA and correlating it with the presence of prostate cancer, the claimed invention, directed to detecting PCGEM1, is described only in the context of an unelected invention directed to detecting prostate cancer. (Office Action at ¶ 13.)

The Applicant respectfully traverses the objection and submits that the specification fully and adequately supports the claims in a context much broader than the detection of prostate cancer. Proper antecedent basis and clear support for the claimed method of detecting PCGEM1 nucleic acids by hybridization are found throughout the specification. Example 7 describes the detection of PCGEM1 RNA in a biological sample by hybridization of PCGEM1 cDNA to normal prostate tissue by Northern blot. The experimental conditions for hybridization are set forth in ¶ 48 of the specification, primers and probes for detecting PCGEM1 are described in ¶¶ 78-79, and methods for hybridization, which are well-known to those of skill in the art, are described in ¶¶ 80-82.

Furthermore, PCGEM1 "DNA may be used in developing treatments for any disorder mediated (directly or indirectly) by defective, or insufficient amounts of PCGEM1." (Specification at ¶ 89, emphasis added.) These disorders are not limited to prostate cancer, nor to prostate-related diseases, and include insulin-dependent diabetes and T-cell leukemia/lymphoma. (Specification at ¶ 88.) They also include prostate-related diseases other than prostate cancer (specification at ¶ 15), including benign prostate hyperplasia. (Specification at ¶ 39). The specification, therefore, supports and provides antecedent basis for the claimed invention and the Applicant respectfully requests the Office to withdraw this objection.

Claims

35 U.S.C. § 101

The Office rejects claims 22-30 as lacking utility, under 35 U.S.C. § 101. According to the Office, the sole use of the claimed methods is to detect a nucleic acid in a biological sample, and this use is not part of the claimed invention. The Office considers the claimed methods of detecting PCGEM1 as a "mere active step" or research tool, without making apparent how they are to be used in a specific and substantial manner, if not to detect prostate cancer. The Office

cited *Brenner, Comm'r. of Patents v. Manson*, 148 U.S.P.Q. (BNA) 689 (U.S. 1966) in its assertion that the claimed invention lacks a "real world" utility because the specification does not disclose a "real world" use. (Office Action at ¶ 15.)

The Applicant respectfully traverses the rejection and asserts that the pending claims have specific, substantial, and credible utility. As stated above, the specification explicitly describes the use of detecting PCGEM1 nucleic acids in any disorder mediated by defective or insufficient amounts of PCGEM1, not only prostate cancer. Detecting the presence of PCGEM1 in a biological sample has the immediately obvious real world utility of detecting a specific, disease-associated nucleotide target.

"An isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it . . . hybridizes near and serves as a marker for a disease gene." (Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (2001).) PCGEM1 has been mapped to the 2q32 region of chromosome 2, a region associated with specific diseases, as described above. (Specification at ¶ 88.) Thus, PCGEM1 serves as a marker for these diseases. The claimed methods further meet the statutory requirements because their utility is specific to PCGEM1, and relates directly to the location and function of the PCGEM1 gene. Their utility is also substantial, as it measures the presence of a compound correlated with medical disorders. Furthermore, their utility is credible, as it would be immediately believable to one of ordinary skill in the art that, within the context of the specification, detecting PCGEM1 nucleic acid in a biological sample can relate to these disorders.

Finally, the Applicant distinguishes its invention from the invention considered by the Supreme Court in *Brenner*. The *Brenner* court decided that a new chemical process lacked utility because, while the invention provided a contribution to scientific research, the chemical itself had no practical use. PCGEM1 nucleic acids have considerable practical use in the detection of diseases associated with the 2q32 region of chromosome 2. Detecting PCGEM1

provides immediate, real-world use and represents the successful conclusion of the Applicant's search. For all the reasons stated above, the Applicant respectfully requests the Office to withdraw the rejection of claims 22-30 under 35 U.S.C. § 101.

35 U.S.C. § 112, Paragraph 1

Enablement

In a context related to its concerns about utility, the Office also rejects claims 22-30 as failing to enable the subject matter of the invention, under 35 U.S.C. § 112, paragraph 1. This corresponding rejection is based on the premise that an invention that lacks utility necessarily fails the enablement requirement for patentability. If a claimed invention lacks utility, a person skilled in the art would be unable to use it, and the specification cannot enable its use. (Office Action at ¶ 15.)

Under the Utility Examination Guidelines, when an Applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under 35 U.S.C. § 101, the Office must not only withdraw the § 101 rejection but must also withdraw the corresponding rejection under 35 U.S.C. § 112, second paragraph. (Utility Examination Guidelines, 66 Fed. Reg. 1092, 1099 (2001).) In view of the arguments presented above, with respect to the utility of the claimed invention, the Applicant respectfully requests the Office to withdraw its rejection under 35 U.S.C. § 112, second paragraph.

Written Description

The Office uses a three-pronged approach to reject claims 22-30 as lacking a written description under 35 U.S.C. § 112, paragraph 1. First it relies on its assessment of utility to assert that detection alone is a mere active step lacking utility, thus does not convey possession to the Applicant. (Office Action at ¶ 21.) Second, the Office asserts that the members of the genus of PCGEM1 nucleic acids may vary substantially and that the specification fails to describe members of the genus as sharing an identifying structural or functional feature. (Office

Action at ¶ 21.) Third, the Office asserts that the specification does not state how a nucleic acid molecule can be detected in the blood and urine, given that nucleic acid molecules are not generally translocated from a cell nor do they remain stable outside the cell. (Office Action at ¶ 21.) The Applicant respectfully traverses with respect to each of these contentions. The Applicant submits that the arguments set forth above with respect to utility render the Office's first ground for rejection moot.

With respect to the Office's second basis for rejection, the Applicant submits that the specification complies with the written description requirement by disclosing the structure of the claimed PCGEM1 nucleic acids. The structure is an example of a relevant, identifying characteristic required by the Written Description Examination Guidelines. (Written Description Examination Guidelines, 66 Fed. Reg. 1099, 1106 (2001).) The claims are directed to a method of detecting a genus of PCGEM1 nucleic acids in a biological sample by hybridization. Members of the genus must hybridize to at least ten contiguous nucleotides of SEQ ID NO:1, thus the scope of the claimed genus is described by SEQ ID NO:1. A person of skill in the art would not expect substantial variation among the nucleic acids encompassed by the claims because hybridization under the moderate to high stringency conditions disclosed in the application yield nucleic acids structurally similar to SEQ ID NO:1. Thus, the disclosed hybridization conditions in combination with the known coding function of DNA disclose the structure of the claimed PCGEM1 nucleic acids. (*See* Revised Interim Written Description Training Examples at Example 9.)

Third, the Applicant replies to the Office's contention that the specification lacks a written description of the detection of nucleic acid molecules in the blood and urine, as they are not generally found outside of a cell. The Applicant traverses, with respect to the amended claims, which specify that PCGEM1 is present in intact cells found in the biological sample. Prostate cells can be found in the blood and one of ordinary skill in the art can detect them using well-

known technologies such as RT-PCR. (*See, e.g.,* Moreno et al., enclosed.) Prostate cells can also be found in the urine and this was known as of March 1999; cells shed from the prostate are transported into the urethra via the prostatic duct system. The Applicant has, therefore, demonstrated possession of the amended claims in the as-filed application and, accordingly, requests that the Office withdraw the rejection of claims 22-30 under 35 U.S.C. § 112, ¶1, with respect to written description.

35 U.S.C. § 112, Paragraph 2

The Office rejects claims 22-30 under 35 U.S.C. § 112, paragraph 2, as indefinite. It characterizes the claims as directed to a mere active step in detecting prostate cancer, a non-elected invention and asks, "[i]f not a mere step in the disclosed process of detecting (diagnosing) prostate cancer, how else might Applicant intend the process, that is now claimed, be used?" (Office Action at ¶ 17.)

The Applicant respectfully traverses the rejection and asserts that the scope of the claim is clear to a person skilled in the art in view of the arguments presented above. The claims are directed to a method of detecting a marker for diseases associated with the 2q32 region of chromosome 2. The claimed methods may be used to detect specific disease-associated nucleotide targets.

The Office asserts an additional ground for rejecting claims 22-30 under 35 U.S.C. § 112, paragraph 2. According to the Office, the hybridization conditions for practicing the claimed invention may vary and, as a result, the claims fail to delineate the metes and bounds of the invention. (Office Action at ¶ 19.)

The Applicant respectfully traverses the rejection. The specification defines conditions under which PCGEM1 nucleic acids in a biological sample can hybridize to the sequences of the invention. (Specification at ¶¶ 48-49.) It explains that a person of ordinary skill in the art can readily determine conditions of moderate and high stringency, cites a standard laboratory

manual, Sambrook et al., that sets forth the basic conditions for both moderate and high stringency (published application at ¶ 49) and discloses that a skilled artisan commonly adjusts these conditions. (*Id.*) The Applicant therefore respectfully requests the Office to withdraw all rejections of claims 22-30 under 35 U.S.C. § 112, second paragraph.

Priority

The Office denied the Applicant's priority claim under 35 U.S.C. §§ 119(e) and/or 120, 121, or 365(c) for benefit of the parent application (Application No. 09/534,072) and Provisional Application 60/126,469, filed March 26, 1999. It states that the earlier-filed applications have not provided an adequate written description or a sufficiently enabling disclosure and contends that the effective filing date is March 18, 2004.

The Applicant respectfully submits that the arguments presented above demonstrate that the provisional application and the parent application provide both adequate written description and a sufficiently enabling disclosure. Citations were made to the paragraph numbers in the published application for ease of reference. The provisional application contains the information relied upon in the arguments presented above and corresponds to the published application as shown in the following chart. Accordingly, the Applicant requests the Office to acknowledge the priority claim and grant the application an effective filing date of March 26, 1999.

Published Application	Provisional Application
Paragraph 15	Page 6, paragraph 3; prostate-related diseases
Paragraph 39	Page 8, paragraph 11; prostate-related diseases
Paragraph 48	Page 10, paragraph 3; hybridization stringency
Paragraph 49	Paragraph spanning pp. 10-11; hybridization stringency
Paragraph 78	Page 17, paragraph 3; primers and probes
Paragraph 79	Page 17, paragraph 3; primers and probes
Paragraph 80	Page 17, paragraph 4; hybridization
Paragraph 81	Page 18, paragraph 1; hybridization
Paragraph 82	Page 18, paragraph 2; hybridization
Paragraph 88	Paragraph spanning pp. 19-20; non-prostate diseases
Paragraph 89	Page 20, paragraph 1; non-prostate diseases
Example 7	Example 6

The Office further contends that, even if claims 22-30 are supported by the disclosure of the provisional application, they do not properly benefit from the filing date of the provisional because the nucleic acid sequence of SEQ ID NO:1 was not described in the provisional application. The Applicant respectfully asserts that the sequence of SEQ ID NO:1 was described in the provisional application.

The Examiner has granted the parent application the benefit of the provisional and, as explained herein, the instant application is a proper continuation of the parent. Thus, the instant application properly claims the benefit of the filing date of the provisional application for the same reasons the parent application properly did so. (Interview Summary Statement of April 8, 2003, U.S. Patent No. 6,828,429.) The Applicant accordingly requests the Office to acknowledge the priority claim and grant the application an effective filing date of March 26, 1999.

35 U.S.C. § 102(b)

Srikantan

The Office rejects claims 22-25 and 27-30 under 35 U.S.C. § 102(b) as anticipated by Srikantan et al., Proc. Natl. Acad. Sci. 97:12216 (2000) ("Srikantan"). An invention properly asserted as anticipatory under 35 U.S.C. § 102(b) must have been published more than one year prior to the Applicant's effective filing date. As set forth above, the Applicant's priority claim reaches back to the date of the related provisional application, thus the effective filing date is March 26, 1999. Srikantan was published after the Applicant's effective filing date thus does not anticipate the claimed invention. The Office is thus respectfully requested to withdraw this rejection.

Dixon and Srikantan

The Office also rejects claims 22-25 and 27-30 under 35 U.S.C. § 102(b) as anticipated by Dixon et al., *Cancer Chemother. Pharmacol.* 43:S78 (1999) ("Dixon"), as evidenced by

Srikantan. Dixon et al. describes work presented at a symposium which took place on September 11-12, 1998. As set forth above, a reference which anticipates the invention under 35 U.S.C. § 102(b) must have been published more than one year prior to the Applicant's effective filing date. Dixon cannot anticipate the application, which, as set forth above, has an effective filing date of March 26, 1999. The Applicant thus respectfully requests the Office to withdraw the rejection under 35 U.S.C. § 102(b) as anticipated by Dixon, as evidenced by Srikantan.

Declaration

The Office considers the Declaration filed in the parent case defective because the instant application claims methods not supported in a manner sufficient to satisfy 35 U.S.C. §§ 101 and 112. The Office asserts the application is properly designated a continuation-in-part, rather than a continuation. The Applicant respectfully traverses in view of the arguments presented above demonstrating that the parent application provides both adequate written description and a sufficiently enabling disclosure. Accordingly, the Applicant requests the Office to acknowledge that the application is a continuation of Application No. 09/534,072 and to enter the as-filed Declaration.

Double Patenting

The Office has rejected claims 22-23 and 27-29 as unpatentable in view of claims 1-9 of U.S. Patent No. 6,828,429. The Applicant respectfully requests that the Office hold this rejection in abeyance until claims 22-23 and 27-29 are allowed.

If there are any fees due in connection with the filing of this preliminary amendment, please charge the fees to Deposit Account No. 06-0916.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 3, 2007

By: _____

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